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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,305	12/06/2001	Charles E. Prussak	041673-2092	1335

30542 7590 09/21/2005

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,305	PRUSSAK ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6,8-14,16-21 and 23-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2-6, 8-14, 16-21, 23-67* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 3/14/05, has been entered.
Claims 1, 7, 15 and 22 have been canceled.
Claims 2-6, 8-14, 16, 18-21, 23-32, 37, 42-44 and 47-51 have been amended.
Claims 52-67 have been added.

Claims 2-6, 8-14, 16-21 and 23-67 are pending.

2. This application appears to be compliant with the Sequence Rules.

3. Applicant is invited to review the claims for proper antecedent basis and /or clarity.
For example, claim 2 is drawn to "a nucleic acid molecule encoding a chimeric TNFα ligand polypeptide", while claim 14 is drawn to "a chimeric TNFα" and not to "a chimeric TNFα ligand polypeptide".
Is there a difference between "a chimeric TNFα" and "a chimeric TNFα ligand polypeptide" ?

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 2-6, 8-13, 27-42, 52-61, drawn to a nucleic acid molecule encoding a chimeric TNFα ligand polypeptide, including vectors, genetic constructs, , host cells and processes of producing said chimeric chimeric TNFα ligand polypeptide, classified in Class 435, subclasses 252.3, 320.1, 326, 455 and in Class 536, subclass 23.1.

II. Claims 14, 16-21, 24-26, 62, drawn to a chimeric TNFα, classified in Class 530, subclass 350.

III. Claims 43-46, drawn to methods of increasing the concentration of a ligand capable of binding to a TNFα receptor by introducing a nucleic acid molecule encoding a chimeric TNFα polypeptide, classified in Class 435, subclass 440.

IV. Claim 47, drawn to methods of inducing apoptosis of a cells by introducing a a nucleic acid molecule encoding a chimeric TNFα ligand polypeptide, classified in Class 435, subclass 440.

Applicant is invited to review the recitation of claim 47, as it appears to be missing the recitation of "a nucleic acid molecule".

V. Claims 48, 64, drawn to methods of inducing activation of an immune system cell by introducing a a nucleic acid molecule encoding a chimeric TNFα ligand polypeptide, classified in Class 435, subclass 440.

VI. Claims49-50, 65-66, drawn to methods of treating neoplasia in a patient by introducing a a nucleic acid molecule encoding a chimeric TNFα ligand polypeptide into a neoplastic cell, classified in Class 435, subclass 440.

VII. Claims 51, 67, drawn to methods of treating neoplasia in a patient by introducing a a nucleic acid molecule encoding a chimeric TNFα ligand polypeptide directly into a tumor be of a patient, classified in Class 514, subclass 44.

4. Inventions I and III/IV/V/VI/VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different processes set forth in Groups I/II/III/V/VIII or can be used to produce proteins of interest.

5. Inventions I and II are different products. Nucleic acid molecules, genetic constructs, vectors, cells, chimeric ligands/proteins are distinct because their structures and modes of action are different. Therefore they are patentably distinct.

Further it is noted that in certain aspects Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)).

Chimeric proteins can be made by a variety of biochemical and recombinant means that differ from that recited in Group I.

6. Inventions III/IV/V/VI/VII are different methods of use. These inventions require different ingredients, process steps and endpoints to accomplish the use of nucleic acids. Therefore they are patentably distinct.

Applicant is invited to clarify the differences between the metes and bounds of Groups III- VII for clarity with respect to both Restriction and prosecution purposes in the interest of compact prosecution.

7. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-VII is not required for any other group from Groups I-VII and Groups I-VII have acquired a separate status in the art as shown by their divergent subject matter, restriction for examination purposes as indicated is proper.

8. In addition to selecting a Group from above, applicant is required to make a species election as well.

(A) This application contains claims directed to the following patentably distinct species of the claimed inventions of Groups I-VII: wherein the product or the product employed in the claimed methods comprises:

A) a first domain,
B) a second domain,
C) a third domain,
D) a fourth domain, or
E) a fifth domain.

These species are distinct because their structures, interactions, modes of action are different. Therefore, they are patentably distinct..

Applicant is required to elect a particular construct as it reads on whether there is one or more domains from (A) above
AND IN ADDITION

(B) Must elect from the following further species as it reads on the appropriate domain such that the domain is:

A) CD154 (CD40 ligand),
B) Fas-ligand,
C) CD70,
D) TNFβ,
E) 4-1BB ligand,
F) TRAIL, or
G) nerve growth factor.

These species are distinct because their structures, interactions, modes of action are different. Therefore, they are patentably distinct.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.
Restriction to one of the following inventions is required under 35 U.S.C. § 121:

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
September 19, 2005